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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,565	03/11/2004	Steven M. Griffiths	008306-0304853	4820
20583	7590	11/01/2007	EXAMINER	
JONES DAY			MACNEILL, ELIZABETH	
222 EAST 41ST ST			ART UNIT	PAPER NUMBER
NEW YORK, NY 10017			3767	
			MAIL DATE	DELIVERY MODE
			11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/797,565

Applicant(s)

GRIFFITHS, STEVEN M.

Examiner

Elizabeth R. MacNeill

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Myerson et al (US 3,063,450)

Regarding claim 1, Myerson teaches a needle and hub assembly for an injection device, comprising: a cap (Fig 1) having an engaging portion (18) adapted to engage an exterior surface (22) of a cartridge (2), and a needle-supporting portion (34) having a wall with a front surface (distal ends of 36) that includes an opening therein, the wall defining interior and exterior surfaces (Fig 1); a first hub portion (11/8) defining a needle-receiving channel (48) through the opening in the wall and having a section that extends along the interior surface of the wall (at 42); a needle (50) mounted in the needle-receiving channel and extending outwardly therefrom; and a second hub portion (12) engaged with the first hub portion (at 55) and receiving at least a portion of the needle, the second hub portion having reinforcing structures (threads at 32) which extend outwardly along the exterior surface of the wall; wherein the wall of the needle-supporting portion of the cap is reinforced on the interior surface by the first hub portion and on the exterior surface by the second hub portion. See Figure 1.

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Regarding claim 8, the second hub portion further comprises a supporting portion (46) that extends along the needle.

Regarding claim 9, the needle-receiving channel provides a continuous flow pathway from the inside of the cap to the outside of the cap (via needle lumen).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myerson.

Myerson teaches the assembly as above. Myerson does not teach that the first and second hub portions are fused. Rather, "the bore of screw cap 12 has a lower tapered portion 55 for cooperating with the external taper 56 of the jaws 11" (Col 4 line 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to fuse the sections together since they are already intended to be mated together securely and it would involve only routine skill in the art to fuse the pieces together, in addition to the added benefit preventing the device from being disassembled.

Regarding claims 3-6, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use metal and plastic to form the device, since it has been held to be within the general skill of a worker in the art to select a known

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material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 7, the reinforcing structures are radially-extending ribs (12).

Claims 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper in view of Sarnoff et al (US 4,755,169).

Regarding claim 10, Myerson teaches a needle and hub assembly for an injection device, comprising: a cap (Fig 1) having an engaging portion (18) adapted to engage an exterior surface (22) of a cartridge (2), and a needle-supporting portion (34) having a wall with a front surface (distal ends of 36) that includes an opening therein, the wall defining interior and exterior surfaces (Fig 1); a first hub portion (11/8) defining a needle-receiving channel (48) through the opening in the wall and having a section that extends along the interior surface of the wall (at 42); a needle (50) mounted in the needle-receiving channel and extending outwardly therefrom; and a second hub portion (12) engaged with the first hub portion (at 55) and receiving at least a portion of the needle, the second hub portion having reinforcing structures (threads at 32) which extend outwardly along the exterior surface of the wall; wherein the wall of the needle-supporting portion of the cap is reinforced on the interior surface by the first hub portion and on the exterior surface by the second hub portion. See Figure 1.

Myerson fails to teach that the assembly is used with an automatic injector with a stored energy source.

Sarnoff teaches an automatic injector with a hub assembly (526), plunger (558), cartridge (546) and a stored energy means (spring 564). See Figs 10-13

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the stored energy means of Sarnoff with the hub assembly of Myerson in order to provide a means for automatically injecting a medicament into a patient by applying less force to the plunger (i.e. allowing the stored energy means to provide force to the plunger).

Regarding claim 11, Myerson does not teach that the first and second hub portions are fused. Rather, "the bore of screw cap 12 has a lower tapered portion 55 for cooperating with the external taper 56 of the jaws 11" (Col 4 line 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to fuse the sections together since they are already intended to be mated together securely and it would involve only routine skill in the art to fuse the pieces together, in addition to the added benefit preventing the device from being disassembled.

Regarding claims 12-15, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use metal and plastic to form the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 16, the reinforcing structures are radially-extending ribs (12).

Regarding claim 17, the second hub portion further comprises a supporting portion (46) that extends along the needle.

Regarding claim 18, the needle-receiving channel provides a continuous flow pathway from the inside of the cap to the outside of the cap (via needle lumen).

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Regarding claim 19, the cartridge has two medicament compartments (552, 540, Sarnoff).

Regarding claim 20, one of the medicament compartments is adapted to house a wet medicament component (552) and the other medicament compartment is adapted to house a dry medicament compartment (540, Sarnoff).

Regarding claim 21, the at least one opening in the cartridge is in the dry medicament compartment (Sarnoff Fig 10).

Response to Arguments

5. Applicant's arguments filed 3 October 2007 have been fully considered but they are not persuasive. Applicant has argued that the end 36 does not contact the first and second hub portion 11/8 and 12. However, distal portion of the wall 34 (shown with the same cross hatching) does contact both the first and second hub portions as claimed (Fig 1). The rejection is maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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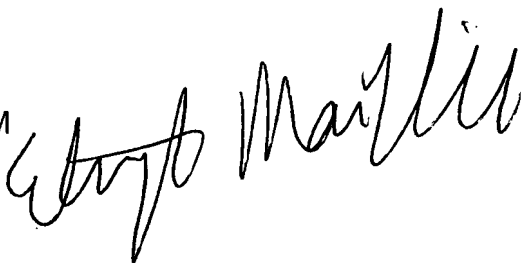
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

